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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,156	12/11/2003	Juan A. Vergez	PHUS-104	5954
24039	7590	10/02/2006	EXAMINER	
INNOVAR, LLC P O BOX 250647 PLANO, TX 75025			SAMALA, JAGADISHWAR RAO	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/733,156

Applicant(s)

VERGEZ ET AL.

Examiner

Jagadishwar R. Samala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- \* Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 9/04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al (US 4,783,337 here after '337) and Theeuwes et al. (US 4,077,407 here after '407) in combination, further in view of Joaquina Faour (US 6,352,721 B1 here after '721).

3. Claims 1-20 are drawn to an osmotic device comprising a core comprising a first amount of therapeutic licofelone agent and at least one osmotic agent or osmopolymer; a semi permeable membrane surrounding the core and having at least one passageway for the delivery of agent.

4. The '337 patent discloses an osmotic device possessing dual osmotic activity that operates as an integrated unit, comprising a compartment containing a first osmotic composition comprising a drug, and preferably an osmopolymer and/or an osmagent, and a second and different osmotic composition with the compositions acting in concert for delivering the drug through a passageway of controlled dimensions from the osmotic device (see column 3, lines 22-31). The '337 patent also discloses the use of osmotic therapeutic device that possesses the ability to delivery drugs over a broad range of drug delivery rates, and can deliver the drugs according to a predetermined drug

release rate pattern to a biological recipient over a desired time period (see column 4, lines 10-15) The '337 patent also discloses the active agents used herein includes any beneficial agent or compound that can be delivered from the device to produce a beneficial and useful results in animals, including warm blooded mammals, humans and primates thereof (see column 19, lines 33+).

5. The '407 patent discloses an osmotic device comprising a wall surrounding a compartment comprising a drug, a agent mixed with an osmotically effective compound, to produce a solution containing agent that is released through the passageway at a controlled and continuous rate over a prolonged period of time. Passageway includes an aperture, orifice or bore through the wall formed by eroding an erodible element in the environment of use (see abstract). The '407 patent also discloses an osmotic device having a wide spectrum of semi permeable walls having distinct properties such as the fluid flow-through rate and agent resistance may be controlled and varied according to desired treatment (see column 2, lines 7-11). The '407 patent also discloses an active agent used herein includes inorganic and organic compounds that are physiologically or pharmacologically active substances that produces a localized or systemic effects in animals, including mammals, humans and primates (see column 18, lines 25-68+)

6. The combination of '337 and '407 teaches most essential elements of the invention, however '337 and '407 patents fails to teach specifically the use of licofelone as one of the pharmacologically active substance that produces a local or systemic effect in humans and primates. The prior art provides tools of powerful osmotic devices for delivering a beneficial agent at controlled and continuous rate over a prolonged

period of time to an environment of use. The use of osmotic device comprising a wall surrounding a compartment and has a passageway through the wall for delivering active agents is well documented. It would have been obvious to one of ordinary skill in the art to further to provide an improved osmotic device for delivering the drugs over a prolonged period of time and also eliminate the necessity for taking multiple doses of drug. Further, it would have been obvious to one of ordinary skill in the art to use an osmotic device that can deliver various therapeutically active agents and has an economic advantage for the user by keeping to a minimum the number of doses to be administrated and reducing missed doses because of forgetfulness.

7. The '721 patent discloses an osmotic device capable of delivering active substances comprising an centrally located core comprising a hydrophilic expandable polymer and, optionally, an osmagent, wherein the core is surrounded by a composition comprising at least one active agent and preferably an osmagent and/or osmopolymer, a membrane immediately surrounding the composition, and at least one preformed passageway and plural micropores in the membrane that communicate the composition with the outside of the device. The '721 patent also discloses a osmotic therapeutic device for the delivery of pharmaceutically active agents, ranging in solubility from slightly soluble to very soluble drugs, in a controlled, continuous and approximately steady, preferably zero order, rate over a prolonged period of time (see column 3, lines 18-33+). The '721 patent further discloses the use of active agents such as biologically or pharmaceutically active agents, medicines, nutrients and other agents that benefit the environment of use (see column 4, lines 4-30).

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It would have been obvious to one of the ordinary skill in the art to provide a preprogrammed, unattended delivery of beneficial drug, that is initially delivered in an increased therapeutically effective amount, followed by delivery of drug at a controlled rate, and for a time period established to meet a specific therapeutic need, because it is known in the art that such programmable osmotic devices for delivery of therapeutic agents have been successfully used to treat or prevent such conditions and diseases. Further it would have been obvious to one of ordinary skill in the art to modify the biologically or pharmaceutically active agents of '337 and '407 thereby, making the drug available instantly to a drug receptor by substantially eliminating the start-up drug delivery time frequently required to deliver some drugs by osmotic device for performing its beneficial effects.

### ***Conclusion***

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**VICKIE KIM**  
**PRIMARY EXAMINER**

Jagadishwar R Samala  
Examiner  
Art Unit 1618

sjr